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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,910	12/16/2003	Ru Chih C. Huang	2240-199065	3871
26694	7590	06/20/2006	EXAMINER	
VENABLE LLP			ROYDS, LESLIE A	
P.O. BOX 34385				
WASHINGTON, DC 20045-9998			ART UNIT	PAPER NUMBER

1614

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/735,910	<b>Applicant(s)</b> HUANG ET AL.	
	<b>Examiner</b> Leslie A. Royds	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 9-16, 18-20 and 22-33 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 9-16, 18-20, 22-33 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### **DETAILED ACTION**

**Claims 9-16, 18-20 and 22-33 are presented for examination. Claims 1-8, 17 and 21 were cancelled pursuant to the Preliminary Amendment filed December 16, 2003.**

#### ***Requirement for Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 9-16, 18-20 and 32-33, drawn to a method for treating a tumor comprising providing a composition comprising an effective amount of the compound recited in claim 9 and applying the composition to the tumor, classified in class 514, subclasses 2 or 529, for example, depending on the agent used.
- II. Claims 22-26, drawn to a method for suppressing Sp1 regulated promoter activity in a cell comprising providing a composition comprising tetra-O-methyl nordihydroguaiaretic acid and exposing the cell to a concentration of this compound, classified in class 424, subclass 7.21, depending on the cell used.
- III. Claims 27-31, drawn to a method of suppressing tumor cell growth comprising providing a composition comprising tetra-O-methyl nordihydroguaiaretic acid and exposing the tumor cell to a concentration of this compound, classified in class 424, subclass 7.23.

The inventions are distinct, each from the other, because of the following reasons:

Inventions I through III are patentably distinct. Inventions are patentably distinct if it can be shown that they have different modes of operation, different functions, or different effects and different resultant endpoints (See MPEP § 806.04, MPEP § 808.01). In the instant case, it is noted that the ultimate objective of Invention I (i.e., treating a tumor) is distinct from the

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objective of Invention II (i.e., suppressing Sp1 regulated promoter activity in a cell), which is distinct from the objective of Invention III (i.e., suppressing tumor cell growth), such that the process steps, compounds, and receiving population (i.e., a tumor vs. any cell) required to execute any one of Inventions I-III are distinctly different such that the steps, compounds and population in which the method is practiced of each invention is unique to the method and is distinctly different from that required in any one or more of the other inventions. In other words, a search in the patent or non-patent literature for one of the methods would not necessarily result in a complete or comprehensive search of the other method because the execution of one method would not reasonably anticipate or render obvious the complete execution of any one or more of the other methods. For these reasons, the methods are considered to be independent and/or patentably distinct.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, different fields of search and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of compounds defined and recited in present claim 1.

The species are independent or distinct because the species of compound(s) recited in the present claims are structurally, functionally, and/or chemically distinct from any one other compound encompassed by the present claims such that a comprehensive search of the patent and non-patent literature for any one such compound would not necessarily result in a comprehensive search of any one or more of the other compounds recited in the claims.

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Notwithstanding that Applicant may have established an underlying common function to this broad genus of compounds, namely, that they are capable of treating tumors, it remains that the art does not necessarily recognize such a shared function as being common to each of the variety of distinct compounds encompassed by the claims. Despite the fact that there may be incidental overlap between any one or more of the compounds contained within the claims, such does not change the fact that each of the compounds encompassed by the claims are distinct from one another because they lack a common physical structure or function and, therefore, are considered patentably distinct. In addition, the discovery of any one of the present claimed compounds would not necessarily anticipate or reasonably suggest or render obvious any one or more of the other compounds of the present claims.

Should Applicant elect Invention I, Applicant is required under 35 U.S.C. 121 to elect a single compound defined in present claim 1 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic to a plurality of compounds.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, identification of each moiety contained within the generic formula (i.e., R1, R2, etc.), a structural depiction of the single elected species of compound and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should Applicant elect an amino acid residue as one of R1-R4, a single disclosed species of amino acid must be elected and stated on the record.

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Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. Please reference MPEP §809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

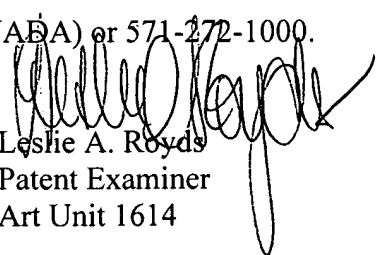
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie A. Royds  
Patent Examiner  
Art Unit 1614

May 26, 2006



ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER